

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions re: Dr. Ricardo Caraballo, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, are the Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Dr. Ricardo Caraballo [ECF No. 4831], and Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Dr. Ricardo Caraballo [ECF No. 4832]. Both motions are now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion [ECF No. 4831] is **GRANTED in part, DENIED in part, and RESERVED in part**, and the plaintiffs' Motion [ECF No. 4832] is **GRANTED in part, DENIED in part, and RESERVED in part**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUT"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with

evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the

relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Caraballo is a board-certified urogynecologist whose practice focuses on female pelvic medicine and reconstructive surgery. He has extensive experience implanting and removing pelvic mesh devices used for the treatment of SUI.

BSC designated Dr. Caraballo as a general causation expert in all Wave 3 cases involving an Advantage, Advantage Fit, or Lynx midurethral sling. The plaintiffs' Motion [ECF No 4831] relates to cases involving an Advantage or Advantage Fit sling. The plaintiffs' Motion [ECF No. 4832] relates to cases involving a Lynx sling. Because the arguments in support of each motion are virtually identical, I will address both motions together in this Order.

A. Safety and Efficacy

First, plaintiffs argue that Dr. Caraballo's opinions on the safety and efficacy of the Advantage and Lynx slings should be excluded because they are not supported by the available medical and scientific literature. According to plaintiffs, Dr. Caraballo's opinions should be excluded because Dr. Caraballo was unable to cite to a single study that compared the Advantage or Lynx to other polypropylene retropubic slings. According to Dr. Caraballo's deposition testimony, however, he states that no study specifically compares the Advantage or Lynx to other polypropylene meshes. Caraballo Dep. 62:14–64:21, Jan. 10, 2015. Dr. Caraballo cited to numerous scientific articles and studies to support his contention that polypropylene mesh slings are generally safe and efficacious. To the extent that Dr. Caraballo is unable to provide scholarship directly comparing the safety and efficacy of the Advantage or Lynx to that of other mesh devices, such matters go to the weight of his opinion, not its admissibility.

Plaintiffs also argue that Dr. Caraballo's opinions concerning the Advantage's safety and efficacy cannot be supported by his independent knowledge or his clinical

experiences. I disagree. Dr. Caraballo has implanted over one thousand Advantage or Advantage Fit devices, in addition to implanting other pelvic mesh devices. Dr. Caraballo has also published multiple articles on polypropylene mesh for the treatment of pelvic floor disorders. Dr. Caraballo's experience and review and contribution to the medical literature provide a reliable basis for his opinions on this issue. To the extent that plaintiffs believe Dr. Caraballo's experience or knowledge is lacking, they may inquire as to these matters during cross-examination. The plaintiffs' Motions on this point are **DENIED**.

B. Adequacy of Warnings

Second, plaintiffs argue that Dr. Caraballo is unqualified to offer opinions on the Advantage's or Lynx's Directions for Use ("DFU"). Plaintiffs state that, not only does Dr. Caraballo admit that he is not an expert in this area, he does not even use the DFU in his practice. Plaintiffs point out that Dr. Caraballo admitted that he did not consult the DFU prior to implanting the Advantage in his patients or before removing the device. Dr. Caraballo opines that the DFU adequately warns of all of the risks and complications that he has personally observed in his practice and that "these devices are not associated with any new risks to patients that I [have] not previously encountered with other pelvic floor surgeries." Caraballo Report 6.

In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear

distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk that they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate merely because it included risks he has observed in his own practice.

Dr. Caraballo does not possess any additional expertise in the specific area of product warnings that would qualify him to offer opinions regarding whether the DFU adequately warns patients of any new risks to patients that he has not previously encountered in his practice. Such opinions are **EXCLUDED**. However, to the extent that the DFU provides warnings specific to the plaintiffs' alleged injuries, Dr. Caraballo is qualified to opine on the adequacy of those warnings. Accordingly, the plaintiffs' Motions on this point are **GRANTED in part** and **DENIED in part**.

C. Properties of Polypropylene

Third, plaintiffs argue that Dr. Caraballo should not be permitted to offer opinions on the properties of polypropylene, specifically foreign body reactions,

shrinkage, and degradation. Plaintiffs challenge Dr. Caraballo's qualifications and the reliability of his opinions.

Dr. Caraballo is an experienced urogynecologist, and he has performed many surgeries implanting and removing polypropylene mesh devices used for the treatment of SUI. I have generally found that such experience qualifies physicians to opine on the properties of polypropylene irrespective of a lack of specialized knowledge of biomaterials. I likewise find that Dr. Caraballo's experience with polypropylene mesh devices sufficiently qualifies him to offer opinions regarding foreign body reaction, shrinkage, and degradation. The plaintiffs' Motions as to this point are **DENIED**.

Plaintiffs challenge the reliability of Dr. Caraballo's opinion on the physical properties of mesh—specifically that the device in question does not degrade, shrink, or cause a foreign body reaction. Dr. Caraballo claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented

with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Caraballo has based his opinions on his extensive clinical experience and a review of the medical and scientific literature; in the abstract, these are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Caraballo did not observe evidence of mesh degradation and shrinkage because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical

community or medical literature can be difficult to assess. Although the expert report indicates Dr. Caraballo reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Caraballo's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

D. Material Safety Data Sheet ("MSDS")

Finally, plaintiffs argue that Dr. Caraballo is unqualified to offer opinions on the MSDS issued by the polypropylene resin manufacturer. Plaintiffs do not challenge the reliability of Dr. Caraballo's opinions, but merely argue that because they believe Dr. Caraballo is unqualified to opine as to the general properties of polypropylene, Dr. Caraballo must likewise be unqualified to offer MSDS opinions. As discussed above, I find that Dr. Caraballo is qualified to opine on certain properties of polypropylene, but I reserved ruling on the reliability of those opinions. I find that as an experienced treating physician, Dr. Caraballo is qualified to offer opinions regarding the extent to which the MSDS is used in medical practice. The plaintiffs' Motions on this point are **DENIED**, and I make no finding as to the reliability of Dr. Caraballo's opinions on this matter.

IV. Conclusion

To summarize, the plaintiffs' Motion concerning [ECF No. 4831] is **GRANTED in part, DENIED in part, and RESERVED in part**, and the plaintiffs' Motion [ECF No. 4832] is **GRANTED in part, DENIED in part, and RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-02443	Allex v. Boston Scientific Corporation
2:17-cv-02202	Atwood v. Boston Scientific Corporation
2:17-cv-01243	Brown v. Boston Scientific Corporation
2:17-cv-02638	Buttke v. Boston Scientific Corporation
2:17-cv-01940	Conley v. Boston Scientific Corporation
2:17-cv-01979	Dunford et al v. Boston Scientific Corporation
2:17-cv-02508	Jeter v. Boston Scientific Corporation
2:17-cv-00047	Long v. Boston Scientific Corporation
2:17-cv-01959	Lowrie v. Boston Scientific Corporation
2:17-cv-02461	Martin v. Boston Scientific Corporation
2:17-cv-00304	Martinez v. Boston Scientific Corporation
2:17-cv-02597	Morgan v. Boston Scientific Corporation
2:17-cv-02524	Murphy v. Boston Scientific Corporation
2:17-cv-00314	Newton v. Boston Scientific Corporation
2:17-cv-00534	Notestine v. Boston Scientific Corporation
2:17-cv-02093	Pamensky Murray v. Boston Scientific Corporation
2:17-cv-02633	Pierson et al v. Boston Scientific Corporation

2:17-cv-02470	Porter v. Boston Scientific Corporation
2:17-cv-02528	Saldivar v. Boston Scientific Corporation
2:17-cv-01938	Schroder v. Boston Scientific Corporation
2:17-cv-02745	Shaw v. Boston Scientific Corporation
2:17-cv-02481	Shepard v. Boston Scientific Corporation
2:17-cv-01845	Shiflet v. Boston Scientific Corporation
2:17-cv-02483	Smith v. Boston Scientific Corporation
2:17-cv-02531	Smith v. Boston Scientific Corporation
2:17-cv-02551	Solomon v. Boston Scientific Corporation
2:17-cv-00528	Sustaita v. Boston Scientific Corporation
2:17-cv-02566	Walker v. Boston Scientific Corporation
2:17-cv-01098	Zeiter v. Boston Scientific Corporation